

Appn. No. 10/813,415

Attorney Docket No. 8627-453  
Client Reference No. PA-5259-RFB/DIV**II. Amendments to the Specification**

Please replace paragraphs [00133] – [00143] with the following amended paragraphs:

**[00133]** Of course, the materials disclosed for use in the present invention **[00134]** can be used in combination with other materials to even greater functional advantage. As just one example, the materials of the present invention could be coextruded with a thin layer of TEFLON® or other lubricious material on its outside or inside diameter. This would add the property of very low friction to a material that could be selectively stiffened or hardened anywhere within a medical device where it would be of advantage.

**[00135] [00134]** The principles of the present invention can also be successfully applied to balloon catheters, and even more advantageously in balloon microcatheters having an outside diameter less than about 1 mm. In general terms, as shown in Fig. 9 the medical device 110 of the present invention can comprise a unitarily and continuously formed portion 108 of varying durometer, the portion 108 comprising a tubular portion 106 and an inflatable balloon 118 unitarily and continuously formed with the tubular portion 106, the balloon 118 and the tubular portion 106 having different durometers. More particularly, the medical device 110 of the present invention can first comprise a catheter shaft 211 having an outer catheter shaft 114 and an inner catheter shaft 112 received in the outer catheter shaft 114, wherein the outer catheter shaft 114 comprises the unitarily and continuously formed portion 108 (without regard to its particular configuration). Advantageously, the outer catheter shaft 114 of the medical device 110 comprises the tubular portion 106 of the portion 108. Preferably, the outer catheter shaft 114 further comprises the inflatable balloon 118, and is unitarily and continuously formed with it. The inflatable balloon 118 has a distal end 119 secured to and sealed to the inner catheter shaft 112, such that the space between the inner and outer catheter shafts 112 and 114 defines a lumen 120 for the delivery and removal of a pressurized inflation fluid to and from the inflatable balloon 118. The inner catheter shaft 112 can include a lumen formed therein (not shown) for receiving a guide wire therein.



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[00136] [00135] The inflatable balloon 118 preferably has a durometer different from that of the outer catheter shaft 114 (or of the unitarily and continuously formed portion 108 or the tubular portion 106). More preferably, the inflatable balloon 118 comprises the preferred materials disclosed above for the discrete inflatable balloon 18. This is readily achieved by allowing the portion 108, whatever its shape or configuration (such as the tubular portion 106) to comprise an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant. The portion 108 preferably comprises at least the first and second parts 102 and 104 described above, unitarily and continuously formed with one another, and at least one of the first and second parts 102 and 104 is exposed to cross-linking irradiation, such that they possess different durometers. The parts 102 and 104 can be exposed to different amounts of cross-linking irradiation, or only one of the parts 102 or 104 can be exposed to cross-linking irradiation while the other is shielded. In this particular embodiment, the balloon 118 is preferably formed from one of the parts 102 or 104, from the tubular part 106 or from the outer catheter shaft 114 by inflation after irradiation and cross-linking. Of course, a separate balloon like the balloon 18 described above can be connected to the outer and inner catheter shafts 114 and 112, and the durometer of one of them (for example, the outer catheter shaft 114) varied in the manner described herein.

[00137] [00136] When constructed from the preferred materials disclosed herein, the inflatable balloon 118 possesses many of the advantageous properties described above with respect to the inflatable balloon 18. Moreover, a medical device 110 having an inflatable balloon 118 unitarily and continuously formed with an outer catheter shaft 114 (or other element disclosed above) can readily be constructed in very small diameters, such as outside diameters below about 1 mm. The problems of precisely forming a fluid inlet/outlet hole through the side of a plural lumen catheter shaft (enabling inflation of a conventional separate balloon mounted on the exterior of the shaft) and securing a separate conventional balloon to such a shaft over such a hole are affirmatively avoided. The resulting medical device 110 possesses the outside diameter of a microcatheter and the superior balloon properties of the irradiation cross-linked materials, and is useful for performing



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angioplasty on very small vessels. In larger diameters, of course, the resulting medical device may be used to deploy a stent in the vascular system of a patient.

**[00138] [00137]** The particular process steps preferred for forming the medical device 110 of the present invention have been described above and need not be repeated in detail. In general, the process steps of the present invention comprise forming the elements disclosed above, irradiating those portions desired to have durometers different from the durometers of the portions not irradiated and assembling the elements into the medical device 110 described

**[00139] [00138]** Similarly, the preferred materials which can be selectively cross-linked in part, by selective irradiation, and employed to construct the medical device 110 of the present invention, have been described in detail above. While such details need not be repeated, it should be remembered that it is particularly preferred that the processes by which the medical device 110 are assembled, are carried out with an irradiation cross-linkable mixture comprising a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl iso-cyanurate and about 10 percent by weight nylon.

**[00140] [00139]** It is believed that the foregoing description clearly demonstrates that the medical device 110 of the present invention possesses significant advantages over prior medical devices. In particular, the present invention provides a medical device 110 which is particularly useful for deploying another medical device such as a stent into a patient, or which is itself to be deployed into a patient, for example, for establishing a passage or lumen in a patient, for expanding a narrowed or obstructed passage or lumen in a patient or for introducing a therapeutic or diagnostic fluid into a patient. The medical device 110 of the present invention advantageously retains a plurality of functions performed in prior devices by discrete or separate elements while eliminating such discrete or separate elements. Moreover, the medical device 110 of the present invention can possess a continuous change in durometer, at least in part, so as to eliminate the locations for kinking or deformation present in prior devices having discrete or separate elements of different durometer.

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**[00141] [00140]** The details of the construction or composition of the various elements of the medical devices 10 and 110 of the present invention not otherwise disclosed are not believed to be critical to the achievement of the advantages of the present invention, so long as the elements possess the strength or mechanical properties needed for them to perform as disclosed. The selection of any such details of construction are believed to be well within the ability of one of even rudimentary skills in this area, in view of the present disclosure. For practical reasons, however, and particularly in the lower outside diameters, the medical devices 10 and 110 of the present invention should probably be considered to be single-use devices, rather than being reusable.

**[00142] [00141]** Industrial Applicability

The present invention is useful for deploying another medical device such as a stent into a patient, or which is itself to be deployed into a patient, for example, for establishing a passage or lumen in a patient, for expanding a narrowed or obstructed passage or lumen in a patient or for introducing a therapeutic or diagnostic fluid into a patient, and therefore finds applicability in human and veterinary medicine.

**[00143] [00142]** It is to be understood, however, that the above-described device is merely an illustrative embodiment of the principles of this invention, and that other devices and methods for using them may be devised by those skilled in the art, without departing from the spirit and scope of the invention. It is also to be understood that the invention is directed to embodiments both comprising and consisting of the disclosed parts and process steps.

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